UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,289	12/12/2003	Jing Zhu	1676.011US1	9939

21186 7590 09/06/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,289	ZHU ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

1a. Claims 1-57 are pending.

1b. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.

II. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:2 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.

III. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with a secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.

IV. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:1

and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.

V. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:4 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.

VI. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:4 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.

VII. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:5 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 514, subclass 12.

VIII. Claims 1-46, drawn in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with a secretory leukocyte protease inhibitor (SLPI), wherein said PEPI comprises the amino acid sequence set forth in SEQ ID NO:5 and the SLPI comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 514, subclass 12.

IX. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:1, classified in class, 530, subclass 351.

X. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:2, classified in class, 530, subclass 351.

XI. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:4, classified in class, 530, subclass 351.

XII. Claims 47-51, drawn in part, to a to a composition comprising a proepithelin (PEPI), which comprises the amino acid set forth in SEQ ID NO:5, classified in class, 530, subclass 351.

XIII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:1 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.

XIV. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:2 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.

XV. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:4 and an SLPI

which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.

XVI. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:5 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:7, classified in class, 530, subclass 351.

XVII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:1 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.

XVIII. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:2 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.

XIX. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:4 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.

XX. Claims 52-57, drawn in part, to a composition comprising a proepithelin (PEPI), which comprises the amino acid sequence set forth in SEQ ID NO:5 and an SLPI which comprises the amino acid sequence set forth in SEQ ID NO:9, classified in class, 530, subclass 351.

The inventions are distinct, each from the other because of the following reasons:

The method of Groups I-VIII are patentably distinct, because the methods employ polypeptides which possess characteristic differences in structure and function, that is distinct for each invention which cannot be exchanged. The polypeptides of SEQ ID Nos: 1, 2, 4 and 5 appear to be distinct polypeptides, which constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the polypeptides is independent and distinct because no common structural or functional properties are described. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

The inventions of Groups IX-XX are patentably distinct, because the recited polypeptides possess characteristic differences in structure and function, that is distinct for each invention which cannot be exchanged. The polypeptides of SEQ ID Nos: 1, 2, 4 and 5, appear to be distinct polypeptides, likewise the polypeptides of SEQ ID Nos: 7 and 9 are patentably distinct, which constitute a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the polypeptides is independent and distinct because no common structural or functional properties are described. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Inventions I-VIII are related to inventions IX-XX as processes of use and products used. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups IX-XX can be used in processes of raising antibodies that bind to the recited polypeptides. Searching the inventions of sequences together would impose serious search burden.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, for example the composition comprising the polypeptide of SEQ ID NO:1, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Having shown that these inventions are distinct for the reasons given above and requirement for separate searches, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR §1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
27 August 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER